EPA WATCH

A twice-monthly survey of environmental regulatory activities undertaken by the EPA, the Department of the Interior, OSHA, the White House, the U.S. Congress, and federal, state and legal agencies

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Congressional Report Faults EPA on ETS Risk Assessment

A Congressionally-mandated report on the potential health effects of environmental tobacco smoke (ETS) raises serious questions about the scientific underpinnings of EPA's controversial January 1993 risk assessment on passive smoking.

In its risk assessment, EPA concluded that ETS is a Group A or known human carcinogen, responsible for about 3,000 lung cancer deaths per year from non-smokers. The agency's findings were cited by numerous groups and government agencies interested in promoting smoking bans in such public places as bars and restaurants as well as in the workplace.

—IN THIS ISSUE—

Senate Passes Bipartisan SDWA Reform, House Likely to Follow P3

House-Senate Conference Restores Some Funding for EPA P4

House Kills Amendment to End Taxpayer-Funded Lobbying by Federal Agencies P6

EPA Eases Up on Compliance Requirements for Small Communities P7

EPA Proposes Loosening Controls on Low-Risk Hazardous Wastes P8

At the time of its release, the agency's ETS risk assessment met with, at best, mixed reviews from scientists and epidemiologists with no ties to the tobacco industry. The issue became the subject of several, sometimes stormy Capitol Hill hearings, and coincided with a Congressional debate, still in progress, over the methodology the agency employs in conducting its risk assessments.

So heated was the debate that Rep. Henry Waxman (D-California) who felt compelled to turn to the non-partisan Congressional Research Service (CRS) -- an independent research arm of Congress -- to render its judgment on the ETS question.

The CRS's findings are contained in "Environmental Tobacco Smoke and Lung Cancer Risk," which was released on November 14 and largely confirms most of the arguments raised against EPA's ETS risk assessment. Although barred by Congress from making specific policy recommendations, the CRS report is nonetheless unsparing in its criticism of the way EPA's risk assessment was carried out and the conclusions the agency drew from its analysis.

EPA based its ETS risk assessment on an analysis of over 30 epidemiologic studies of lung cancer among adult non-smoking women. These studies, in turn, relied on spousal smoking as a surrogate for ETS exposure and classified the women as "exposed" or "unexposed" on the basis of whether their husbands smoked. The lung cancer risk among the exposed women was then compared to that of the unexposed women. EPA then carried out a rarely-used statistical exercise known as a meta-analysis and concluded that exposure to ETS increased the overall risk of lung cancer in non-smoking women by 1.19 to 1.

"Subject to Uncertainty"

Since so much of the epidemiologic data used in the studies EPA analyzed were based, among other things, on the sometimes faulty memories (recall bias) of the individuals interviewed, the results, as the CRS warns, are to be viewed with caution.

"The results are not definitive, the CRS observes. "And even at the greatest (exposure) levels, the measured risks are still subject to uncertainty." Contradicting EPA's estimates of 3,000 deaths annually as a result of exposure to ETS, the CRS finds that "it is possible that very few or even no deaths can be attributed to ETS."

Acknowledging that three of the four most recent epidemiologic studies on ETS and lung cancer risk found a "statistically significant exposure risk" for lung cancer at the "highest" secondhand smoke exposure levels, the CRS cautions that,

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"Even at the greatest . . . exposure levels, the measured risks are still subject to uncertainty."

Focusing on the agency's methodology, the CRS found fault with EPA's meta-analysis of the results of numerous individual studies. The CRS noted that "combining risk assessments of several studies at the highest exposure levels probably yields misleading results."

Additional uncertainty enters the picture through what is known as exposure misclassification, the CRS points out. Misclassification occurs when, in the case of EPA's ETS risk assessment, a control group member identifies herself as having a smoking husband but is actually unexposed to ETS, but is still incorrectly counted as exposed. Adjusting for such exposure misclassification would thus increase the measured relative risk.

"It is clear that misclassification and recall bias plague ETS epidemiology studies," the CRS observes. "It is also clear from the simulations that modest, possible misclassification and recall bias rates can change the measured relative risk results, possibly in dramatic ways," the report continues.

Biological Plausibility Challenged

Perhaps the most devastating criticism the CRS made concerns the biological plausibility of EPA risk assessment. The report points out that the chemical similarities between mainstream and sidestream smoke and the association of active smoking with lung cancer are reasons for a possible relationship between ETS and lung cancer. "But," the report says, "they do not prove the relationship, since ETS is substantially diluted and aged compared to even low levels of active smoking. Distancing itself from EPA's direct extrapolation from active to passive smoking, the CRS observes that, "It is possible that ETS exposures are too small to be the cause of lung cancer in any meaningful sense..."

In sum, the report confirms the findings the CRS made last year in testimony before a Senate subcommittee that, "The statistical evidence does not appear to support a conclusion that there are substantial health effects of passive smoking."

OSHA Fares No Better

EPA is not the only Federal agency the CRS criticizes for its handling of ETS. Last year, the Occupational Health and Safety Administration (OSHA) proposed to regulate indoor air quality (IAQ) in the workplace. OSHA's proposal included a ban on workplace smoking, except in designated and separately ventilated areas. OSHA based its proposed workplace smoking ban largely on EPA's ETS findings, but also carried out a risk assessment of its own. The latter fared no better in the CRS report than did EPA.

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"OSHA concluded that the ETS lung cancer risk ranges from 1.20 to 1.50," the CRS points out. "It does not provide any explanation of how it arrives at this explanation or how it arrived at this estimate . . . nor did it indicate what this risk is relative to."

For OSHA, the CRS's rebuke is particularly embarrassing, because it is the second government-funded study issued this year critical of the agency's ETS risk assessment. A Department of Energy publication, "Choices in Risk Assessment: The Role of Science Policy in the Environmental Risk Management Process," echoed the CRS by noting that, "OSHA did not provide an explicit rationale for the science policy decision that chronic exposure to ETS increases lung cancer risk by 20 to 50 percent."

New Hearings Demanded

Armed with the CRS's findings, opponents of OSHA's proposed smoking rules lost little time in blasting EPA and OSHA for their handling of the ETS issue. Sen. Wendell Ford (D-Kentucky and the minority whip in the Senate) called on OSHA to reopen hearings on the proposed smoking ban. "This report from CRS -- a non-partisan and objective organization -- shows there is absolutely no scientific justification for smoking bans or de facto bans like the proposed rule coming out of OSHA," he said.

The sentiments of the Kentucky lawmaker, whose state is a major tobacco producer, were echoed by a host of trade associations directly affected by the pending OSHA rule, including the National Restaurant Association, the U.S. Chamber of Commerce, and the National Licensed Beverage Association. By contrast, EPA, OSHA, and Rep. Waxman's office issued no statements on the CRS's findings.

It is a virtual certainty that the CRS report will reignite debate in Washington over the role of sound science in Federal government risk assessments. Just five months ago, EPA's risk assessment on dioxin, over four years in making, was shelved by the agency's Science Advisory Board and sent back to EPA with the clear recommendation that a crucial chapter be completely rewritten (see EPA WATCH, July 15, 1995, p. 1). ♦

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